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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

STRZELECKA, TERESA E

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 04/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/673,884

Applicant(s)

ASADA ET AL.

Examiner

Teresa E. Strzelecka

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16,18,21-23 and 31-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16,18,21-23 and 31-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/9/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This case has been transferred to examiner Teresa Strzelecka because examiner Spiegler left the USPTO.

2. This office action is in response to an amendment filed January 25, 2005. Claims 1, 5-9, 16-18, 21-23 and 31-35 were previously pending. Applicants cancelled claims 1, 5-9 and 17, and amended claims 16, 18, 21, 22 and 31. Claims 16, 18, 21-23 and 31-35 are pending and will be examined.

3. Applicants' amendments and claim cancellations overcame the following rejections: rejection of claims 1, 16 and 17 under 35 U.S.C. 102(b) as anticipated by Blakely et al.; rejection of claims 1, 16-18, 21 and 31-34 under 35 U.S.C. 102(e) as anticipated by Koster et al.; rejection of claims 1, 16-18, 21-23 and 31-35 under 35 U.S.C. 102(e) as anticipated by Sorge et al.; rejection of claims 1, 6-8 and 16 under 35 U.S.C. 102(b) as anticipated by Barton; rejection of claims 1, 5-9, 16-18, 21 and 31-35 under 35 U.S.C. 112, first paragraph, written description; rejection of claims 1, 5-9, 16-18, 21, 22 and 31-35 under 35 U.S.C. 112, second paragraph; rejection of claims 1 and 16 under 35 U.S.C. 102(b) as anticipated by Sigma Catalog; rejection of claims 1, 5 and 16 under 35 U.S.C. 102(e) as anticipated by Sakai et al. and rejection of claims 1, 6-9 and 16 under 35 U.S.C. 102(e) as anticipated by Tavitigian et al. Rejection of claims 22, 23 and 35 under 35 U.S.C. 102(e) as anticipated by Koster et al. is maintained for reasons given in the "Response to Arguments" section below.

4. This office action contains new grounds for rejection necessitated by amendment.

Information Disclosure Statement

5. The information disclosure statement (IDS) submitted on February 9, 2005 was filed after the mailing date of the non-final office action on August 25, 2004. The submission is in compliance

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with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Response to Arguments

6. Applicant's arguments filed January 25, 2005 have been fully considered but they are not persuasive.

A) Regarding the rejection of claims 22, 23 and 35 under 35 U.S.C. 102(e) as anticipated by Koster et al., Applicants argue that claims do not recite "cationic complex", which was interpreted by the examiner as Mg^{2+} . However, neither claim 22 or 23 recite a limitation of a transition metal complex, and claim 35, dependent from claim 22, recites "cationic complex". Therefore the rejections are maintained with respect to these claims.

Claim Interpretation

7. The term "DNA-synthesis reaction-enhancer" in claim 16, 31 and 35 does not refer to a structural feature of any of the compound listed in these claims, therefore it is not considered when the claimed subject matter is compared with prior art.

8. The phrase "transition metal complex" has not been defined by Applicants, therefore any compound comprising a transition metal is considered to anticipate this term.

9. The phrases " α -type polymerase" and "non- α , non-pol I type DNA polymerase" have not been defined by Applicants, therefore any polymerase is considered to anticipate these terms.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claim 16 is rejected under 35 U.S.C. 102(b) as being anticipated by Demeke et al.

(Biotechniques, vol. 12, pp. 332, 334, 1992; cited in the IDS).

Demeke et al. teach DNA synthesis reaction compositions comprising Taq DNA polymerase and one of the following polysaccharides: carrageenan, pectin and dextran sulfate, together with reaction components necessary for DNA synthesis (Abstract; page 332, second paragraph; Table 1). Therefore, Demeke et al. anticipate the limitations of claim 16.

12. Claim 16 is rejected under 35 U.S.C. 102(b) as being anticipated by Tasa et al. (Meth. Mol. Cel. Biol., vol. 5, pp. 122-124, 1995; cited in the IDS).

Tasa et al. teach a DNA synthesis reaction comprising a Taq DNA polymerase and heparin together with reaction components necessary for DNA synthesis (Abstract; page 123, second paragraph and paragraph entitled "Methodology"). Therefore, Tasa et al. anticipate the limitations of claim 16.

13. Claim 16 is rejected under 35 U.S.C. 102(b) as being anticipated by Loeb et al. (U.S. Patent No. 4,072,574).

Loeb et al. teach a DNA synthesis reaction composition comprising an AMV DNA polymerase and one of the following transition metal complexes of silver, cobalt, chromium, copper, iron, manganese and nickel together with reaction components necessary for DNA synthesis (col. 4, lines 44-60; Table 1). Therefore, Loeb et al. anticipate the limitations of claim 16.

14. Claim 16 is rejected under 35 U.S.C. 102(b) as being anticipated by Diringer et al. (U.S. Patent No. 5,153,181).

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Diringer et al. teach a DNA synthesis composition comprising SR-D reverse transcriptase (= DNA polymerase) and one of the following compounds: chondroitin sulfate, heparin, dextran sulfate together with reaction components necessary for DNA synthesis (col. 4, lines 23-39). Diringer et al. also teach polyvinyl sulfates (col. 3, lines 14-16). Therefore, Loeb et al. anticipate the limitations of claim 16.

15. Claims 22, 23 and 35 are rejected under 35 U.S.C. 102(e) as being anticipated by Koster et al. (U.S. Patent No. 5,928,906; cited in the previous office action).

Regarding claim 22, Koster et al. teach the composition comprising two or more kinds of DNA polymerase having 3'-5' exonuclease activity that is not reduced (col. 7, lines 43-67; col. 8, lines 1-12).

Regarding Claim 23, Koster teaches the composition comprising an α -type DNA polymerase and a non α -type DNA polymerase (col. 7, lines 43-67; col. 8, lines 1-12).

Regarding claim 35, Koster et al. teach a composition comprising two DNA polymerases and Mg^{2+} (col. 12, lines 19-37), therefore, Koster et al. teach a composition comprising a cationic complex.

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Rejections based on the Demeke et al. reference

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17. Claims 18 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Demeke et al. (Biotechniques, vol. 12, pp. 332, 334, 1992; cited in the IDS) and Barnes (U.S. Patent No. 5,436,149 A).

A) Demeke et al. teach DNA synthesis composition comprising a DNA polymerase, but do not teach a composition comprising two DNA polymerases or a composition comprising one polymerase with 3'-5' exonuclease activity and one polymerase without such activity.

B) Barnes teaches a composition comprising two DNA polymerases, one with 3'-5' exonuclease activity and one without such activity (col. 3, lines 62-67; col. 4, lines 1-11; col. 16, lines 55-61).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to have used two polymerases with different 3'-5' exonuclease activities of Barnes in the composition of Demeke et al. The motivation to do so, provided by Barnes, would have been that using such polymerase combination allowed amplification of long DNA targets (col. 16, lines 55-61).

18. Claims 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Demeke et al. (Biotechniques, vol. 12, pp. 332, 334, 1992; cited in the IDS), Barnes (U.S. Patent No. 5,436,149 A) and Stratagene Catalog (page 39, 1988).

A) Demeke et al. teach Taq, a thermostable DNA polymerase, and a composition of claim 16, including reagent usable for DNA synthesis (dNTPs, for example) but do not teach kits comprising a composition of claim 16 or two DNA polymerases.

B) Barnes teaches compositions comprising two DNA polymerases and suggests kits by teaching formulations comprising two DNA polymerases, where at least one of the polymerases is thermostable (col. 38, lines 66-68; col. 39, col. 40).

C) Stratagene catalog teaches a motivation to combine reagents into kit format (page 39).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine the compositions of Demeke et al. and Barnes into a kit format as discussed by Stratagene catalog since the Stratagene catalog teaches a motivation for combining reagents of use in an assay into a kit, "Each kit provides two services: 1) a variety of different reagents have been assembled and pre-mixed specifically for a defined set of experiments. Thus one need not purchase gram quantities of 10 different reagents, each of which is needed in only microgram amounts, when beginning a series of experiments. When one considers all of the unused chemicals that typically accumulate in weighing rooms, desiccators, and freezers, one quickly realizes that it is actually far more expensive for a small number of users to prepare most buffer solutions from the basic reagents. Stratagene provides only the quantities you will actually need, premixed and tested. In actuality, the kit format saves money and resources for everyone by dramatically reducing waste. 2) The other service provided in a kit is quality control" (page 39, column 1).

Rejections based on the Tasa et al. reference

19. Claims 18 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tasa et al. (Meth. Mol. Cel. Biol., vol. 5, pp. 122-124, 1995; cited in the IDS) and Barnes (U.S. Patent No. 5,436,149 A).

A) Tasa et al. teach DNA synthesis composition comprising a DNA polymerase, but do not teach a composition comprising two DNA polymerases or a composition comprising one polymerase with 3'-5' exonuclease activity and one polymerase without such activity.

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B) Barnes teaches a composition comprising two DNA polymerases, one with 3'-5' exonuclease activity and one without such activity (col. 3, lines 62-67; col. 4, lines 1-11; col. 16, lines 55-61).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to have used two polymerases with different 3'-5' exonuclease activities of Barnes in the composition of Tasa et al. The motivation to do so, provided by Barnes, would have been that using such polymerase combination allowed amplification of long DNA targets (col. 16, lines 55-61).

20. Claims 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tasa et al. (Meth. Mol. Cel. Biol., vol. 5, pp. 122-124, 1995; cited in the IDS), Barnes (U.S. Patent No. 5,436,149 A) and Stratagene Catalog (page 39, 1988).

A) Tasa et al. teach Taq, a thermostable DNA polymerase, and a composition of claim 16, including reagent usable for DNA synthesis (dNTPs, for example) but do not teach kits comprising a composition of claim 16 or two DNA polymerases.

B) Barnes teaches compositions comprising two DNA polymerases and suggests kits by teaching formulations comprising two DNA polymerases, where at least one of the polymerases is thermostable (col. 38, lines 66-68; col. 39, col. 40).

C) Stratagene catalog teaches a motivation to combine reagents into kit format (page 39).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine the compositions of Tasa et al. and Barnes into a kit format as discussed by Stratagene catalog since the Stratagene catalog teaches a motivation for combining reagents of use in an assay into a kit, "Each kit provides two services: 1) a variety of different reagents have been assembled and pre-mixed specifically for a defined set of experiments. Thus one need not purchase gram quantities of 10 different reagents, each of which is needed in only

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microgram amounts, when beginning a series of experiments. When one considers all of the unused chemicals that typically accumulate in weighing rooms, desiccators, and freezers, one quickly realizes that it is actually far more expensive for a small number of users to prepare most buffer solutions from the basic reagents. Stratagene provides only the quantities you will actually need, premixed and tested. In actuality, the kit format saves money and resources for everyone by dramatically reducing waste. 2) The other service provided in a kit is quality control" (page 39, column 1).

21. No claims are allowed.

Conclusion

22. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa E. Strzelecka whose telephone number is (571) 272-0789. The examiner can normally be reached on M-F (8:30-5:30).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TS
April 7, 2005


JEFFREY FREDMAN
PRIMARY EXAMINER
4/14/05